

2022-1293, -1294, -1295, -1296

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

IN RE CELLECT, LLC,

Appellant.

Appeal from the United States Patent and Trademark Office,
Patent Trial and Appeal Board in *Ex Parte* Reexamination Control Nos. 90/014,453,
90/014,454, 90/014,455, 90/014,457.

**BRIEF FOR APPELLEE, DIRECTOR OF THE
UNITED STATES PATENT AND TRADEMARK OFFICE**

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Illustrative Claims

U.S. Patent No. 6,982,742

42. In a PDA having capability to transmit and receive data in a communications network, the improvement comprising:

a video system integral with said PDA for receiving and transmitting video images, and for viewing said images, said video system comprising:

a camera module housing an image sensor therein, said image sensor lying in a first plane and including an array of pixels for receiving images thereon, said image sensor producing a pre-video signal, a first circuit board lying in a second plane and electrically coupled to said image sensor, said first circuit board including circuitry means for timing and control of said array of pixels and circuitry means for processing and converting said pre-video signal to a desired video format, a transceiver radio element communicating with said first circuit board for transmitting said converted pre-video signal;

a transceiver radio module mounted in said PDA for wirelessly receiving said converted pre-video signal; and

a video view screen attached to said PDA for viewing said video images, said video view screen communicating with said transceiver radio module, and displaying video images processed by said first circuit board.

U.S. Patent No. 6,424,369

49. In a PDA having capability to transmit data between a personal computer connected to a communications network, the improvement comprising:

a video system integral with said PDA for receiving and transmitting video images, and for viewing said images, said video system comprising:

a camera module housing an image sensor therein, said image sensor lying in a first plane and including an array of CMOS pixels for receiving images thereon, said image sensor producing a pre-video signal, a first circuit board lying in a second plane and electrically coupled to said image sensor, said first circuit board including circuitry means for timing and control of said array of CMOS pixels and circuitry means for processing and converting said pre-video signal to a desired video format; and a video view screen attached to said PDA for viewing said video images, said video view screen communicating with said first circuit board.

U.S. Patent No. 6,452,626

1. In a wireless telephone for conducting wireless telephonic communications, the improvement comprising:

a video system integral with said telephone for receiving and transmitting video images, and for viewing said video images, said video system comprising;

a camera module housing an image sensor therein, said image sensor lying in a

first plane and including an array of CMOS pixels for receiving images thereon, said image sensor further including circuitry means on said first plane and coupled to said array of CMOS pixels for timing and control of said array of CMOS pixels, said image sensor producing a pre-video signal, a first circuit board lying in a second plane and electrically coupled to said image sensor, said first circuit board including circuitry means for converting said pre-video signal to a desired video format;

a video monitor attached to said wireless phone for viewing said video images, said video monitor communicating with said first circuit board, and displaying video images processed by said first circuit board.

U.S. Patent No. 7,002,621

33. In a video telephone for receiving and transmitting telephone communications to include video signals transmitted by the user of the phone, and video signals received from the party to whom a call is made, the video telephone including a video monitor for viewing the video signals, the improvement comprising:

a camera module for taking video images, said camera module communicating with circuitry within said video enabling video signals to be transmitted from said camera module to said video telephone for viewing by said user or for further transmission to another party, said camera module including an image sensor housed therein and lying in a first plane, said image sensor including an array of pixels for receiving images thereon, said image sensor producing a pre-video signal, and a transceiver radio element communicating with said image sensor for wirelessly transmitting said pre-video signal.

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Statement of Related Cases

The Director is not aware of any other appeal in connection with the Patent Trial and Appeal Board (“Board”) proceeding below that was previously before this or any other court. Beyond the cases identified in Cellect’s opening brief that relate to Cellect’s patents-in-suit (Br. at 1), the Director is unaware of any other case pending in this or any other court that will directly affect, or be directly affected by, the Court’s decision in this appeal.

I. Introduction

This appeal is primarily about whether a straightforward application of obviousness-type double patenting, first raised in *ex parte* reexamination as to expired patents, is proper when the difference in patent term between claims in the reference patents and challenged patents is due to patent term adjustment (“PTA”). As the Board correctly determined, it is.

A fundamental tenet of patent law is that once a patent expires the public is free to use the claimed invention. A patent holder cannot extend the life of a patent by sequentially securing patents directed to essentially the same invention. This doctrine is known as obviousness-type double patenting (“ODP”), and it stops a patentee from unjustifiably extending her right to exclude others via claims in a later expiring patent that are not patentably distinct over claims in a commonly-owned earlier expiring patent. As this Court has previously explained, the ODP doctrine polices this problem of a second, later-expiring patent for the same invention that arises when a patentee secures patents claiming overlapping subject matter that are filed on the same day but have different patent terms due to PTA. *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. Of Rheumatology Tr.*, 764 F.3d 1366, 1373 (Fed. Cir. 2014) (explaining that “[w]hen such situations arise, the doctrine of obviousness-type double patenting ensures that a particular invention (and obvious variants thereof) does not receive an undue patent term extension”); *see also In re Fallaux*, 564 F.3d 1313, 1319 (Fed. Cir. 2009) (explaining that “in some cases there may still be the

possibility of an unjust time-wise extension of a patent arising from patent term adjustment under § 154”).

Under the Patent Act, a patent generally expires 20 years after the earliest effective U.S. filing date of the patent application from which it issued. 35 U.S.C. § 154(a)(2). Because the expiration date is calculated from the date of filing, and delays in prosecution of a patent application can reduce the enforceable term of a patent, in 1999, Congress amended Section 154 and authorized PTA for certain examination delays by the USPTO. Pub. L. No. 106-113, § 1000(a)(9), 113 Stat. 1501, 1536 (1999) (codified at 35 U.S.C. § 154(b)). But in doing so, Congress plainly specified that any PTA provided by the statute is done subject to a terminal disclaimer. 35 U.S.C. § 154(b)(2)(B).

In the case at bar, Collect obtained several related patents, all directed to similar electronic communication devices comprising solid state image sensors, and all claiming priority to the same parent application. Collect does not contest that the claims in these patents are directed to patentably indistinct subject matter. Due to delays during prosecution, and as Collect’s patents were not subject to terminal disclaimers, several of Collect’s patents received PTA pursuant to 35 U.S.C. § 154(b). But for the PTA, the patents would have expired on the same day. As a result, Collect secured several patents claiming patentably indistinct electronic devices that have the same effective filing date, but different later expiration dates, and thereby unduly extending its right to exclude the public from practicing those inventions.

In four reexamination proceedings, the Board concluded that Collect's challenged patent claims are obvious variants of Collect's prior-expiring reference patent claims, and thus unpatentable under ODP. Collect did not dispute that the challenged patents and reference patents are commonly owned, that the challenged patents expired after the reference patents, and that all of the challenged claims are patentably indistinct over the reference claims. And because Collect's reference patents had expired, Collect conceded it could not obviate the rejection with a terminal disclaimer. Collect instead focused its arguments on whether an ODP rejection can stand under legal principles when the difference in patent term (i.e., expiration date) is due to statutorily granted PTA, and whether such a rejection is proper under equitable principles when no terminal disclaimer can be filed to cure the rejection but Collect has promised not to sell its expired patents. Collect also argued that the reexamination request itself was not properly granted as not presenting a substantial new question of patentability.

Collect's legal argument largely rested on this Court's decision in *Novartis AG, et al., v. Ezra Ventures LLC*, 909 F.3d 1367, 1373 (Fed. Cir. 2018), which held that ODP does not invalidate a validly obtained patent term extension ("PTE") authorized under 35 U.S.C. § 156. Collect argued that the Board should similarly find that ODP cannot negate a statutory grant of PTA. Based on this Court's precedent acknowledging that ODP applies when the unjustified extension is due to PTA; the statutory difference in the PTA and PTE statutes, where Section 154 excludes patents in which a terminal

disclaimer was filed from the benefit of PTA beyond the expiration date specified in the disclaimer, while Section 156 has no such cutoff; and this Court's decisions in *Ezra* and *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317 (Fed. Cir. 2007) which were premised on that statutory difference, the Board found Collect's arguments to be unpersuasive and properly affirmed the Examiner's rejections of Collect's claims.

Collect's equitable argument fared no better. That Collect could not file a terminal disclaimer during the reexamination was of no moment; if Collect had wanted retain separate patents on its patentably indistinct inventions, it could have filed preemptive terminal disclaimers during the original prosecution of its patents. As a consequence of not doing so, Collect enjoyed an unjustified extension of its right to exclude the public from its claimed invention once the reference patent expired. Also, as the Board found, Collect's promise not to sell its patents was not sufficient, as the patents could have been involuntarily split among other owners by a bankruptcy proceeding. Finally, because there is no basis to conclude, under 35 U.S.C. § 303(a) and this Court's decision in *In re Vivint*, 14 F.4th 1342, 1349 (Fed. Cir. 2021), that the Examiner considered and decided the issue of ODP during the original prosecution of the applications that matured into Collect's challenged patents, the Board properly rejected Collect's argument that the reexamination did not present a substantial new question of patentability. For these reasons, and as further explained below, the Board's decision should be affirmed.

II. Statement of the Issues

The issues on appeal include:

1. Whether the Board erred in determining that Collect's earlier expiring patent qualified as an ODP reference against Collect's later-expiring patent, where there is a timewise extension of the right to exclude the public from practicing obvious variants of the invention due to PTA.
2. Whether an ODP rejection should stand when a terminal disclaimer cannot be filed to retroactively cure the rejection over an expired reference patent.
3. Whether a substantial new question of patentability was raised in the reexamination request where there is no evidence the Examiner considered and decided whether the challenged claims were patentably distinct over the asserted reference patent claims during original prosecution.

III. Statement of the Case

This appeal arises from four reexamination proceedings concerning U.S. Patent Nos. 6,982,742; 6,424,369; 6,452,626; and 7,002,621 (collectively, the "challenged patents," individually, "the '742 patent," "the '369 patent," "the '626 patent," and "the '621 patent") all owned by Collect. *See* Br. at 10.¹

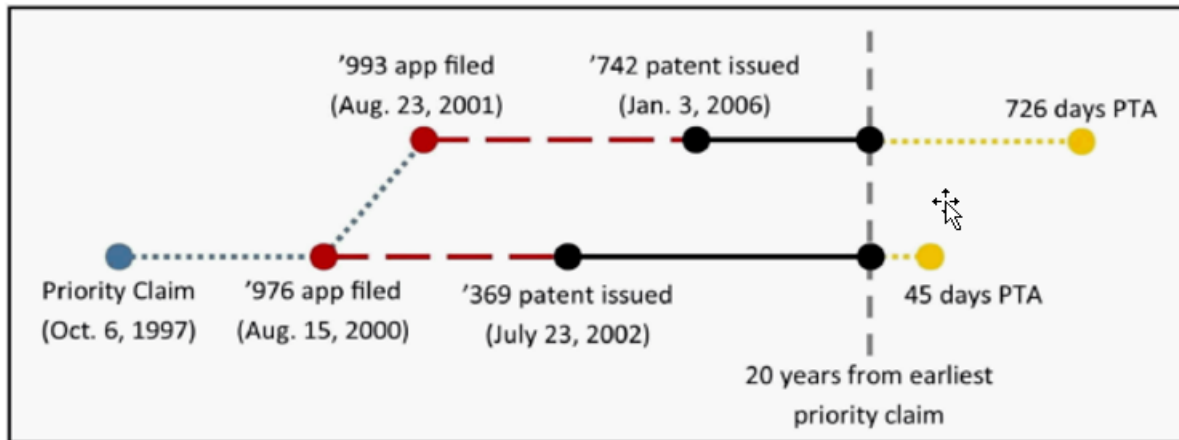
¹ Citations to the joint appendix are denoted as "Appx___," and citations to Collect's brief are denoted as "Br. at ___."

A. Collect's challenged patents claim inventions that are patentably indistinct over Collect's related, but earlier expired, patents.

The challenged patents are all directed to and claim small electronic devices (e.g., personal digital assistant devices or phones) that comprise image sensors. *See, e.g.*, the '742 patent at claim 22 (Appx120); the '369 patent at claim 1 (Appx123); the '626 patent at claim 1 (Appx126); and the '621 patent at claim 25 (Appx130). These patents also all claim priority to U.S. Application No. 08/944,322, which was filed on October 6, 1997. Br. at 10-11; Appx1654. Though the challenged patents ordinarily would have expired on October 6, 2017, they received patent term adjustment under 35 U.S.C. § 154(b) due to delays in prosecution, which extended the patent term beyond twenty years from the priority date, and, at issue here, resulted in patent terms that extended beyond the terms of certain prior-issued claims which Collect does not dispute are patentably indistinct (*see e.g.*, Appx5).

For example, Collect's '369 patent and '742 patent claim priority to that same parent '322 application, but upon issuance were granted PTA due to examination delay. Appx5.² As the figure below demonstrates, while the '369 patent received 45 days of PTA, the '742 patent received 726 days of PTA and thus expired much after the '369 patent:

² Because the issues in all four reexamination proceedings are the same, the Director largely cites to Reexamination Serial No. 90/014,453 as representative.



Id.

After these patents had expired, but while still being enforced by Collect in litigation³, a reexamination (Serial No. 90/014,453) was requested and instituted to determine whether particular claims of the '742 patent were an obvious variation of claims of the '369 patent, and thus unpatentable under ODP. Appx1654-1664. In determining that a substantial new question of patentability was raised, among other things, the Examiner explained that during the original prosecution of the application that matured into the '742 patent, no double patenting analysis was presented. Appx1660; Appx3606; *see also* Appx437 (during the prosecution of the application that matured into the '742 patent, the Examiner issued a single office action rejecting pending claims under 35 U.S.C. § 103 in view of other prior art); Appx528 (following Collect's response, in the next action the Examiner allowed the pending claims).

³ See *Collect, LLC v. Samsung Electronics Co., Ltd., et al.*, No. 1:19-cv-00438 (D. Colo.).

In the reexamination, the Examiner subsequently issued a final office action determining the challenged claims of the '742 patent to be unpatentable under ODP over the reference claims of Collect's prior-expiring '369 patent. Appx3598-3626; *see also* Appx3973-3978 (Examiner's Advisory Action); Appx4104-4114 (Examiner's Answer). Collect appealed the Examiner's decision to the Board, but did not argue that the challenged claims in Collect's '742 patent are patentably distinct over the reference claims in the '369 patent. *See* Appx4010-4011 (listing the other issues Collect appealed to the Board). And because the '369 patent and '742 patent had already expired, Collect conceded it could not overcome the ODP rejection with a terminal disclaimer over the reference patent. Appx4024 ("However, filing a terminal disclaimer now is not possible as the patents are expired"). A similar sequence of events occurred as to claims in Collect's other challenged patents. *See e.g.*, Appx5114-5136; Appx6100-6181; Appx6201-6229; Appx6336-6356; Appx7406-7419; Appx9030-9064; Appx9218-9238; Appx10851-10869; Appx11905-11938; Appx11975-11979; Appx12078-12091.

B. The Board's determination that Collect's challenged patent claims are unpatentable under ODP over claims in Collect's earlier expiring patents.

In each of the underlying reexaminations, the Board affirmed the Examiner's rejection of claims in Collect's challenged patents as unpatentable on at least one ground of obviousness-type double patenting over claims in Collect's prior-expiring

patents. Appx1-97.⁴ As Collect did not contest that those challenged claims were patentably indistinct over the cited reference claims (*see e.g.*, Appx5), the Board focused on Collect's assertions that (1) the reference patent cannot be used as an ODP reference because the difference in patent term is due to PTA; (2) the rejection should not be enforced because no terminal disclaimer could be filed to overcome the ODP rejection as the reference patent has expired; and (3) there was no substantial new question of patentability because the same examiner examined all of the applications that led to the challenged patents and he was aware of the reference patents. But the Board found Collect's arguments to be unpersuasive and affirmed the Examiner's rejections. Appx5-24; *see also* Appx29-49; Appx55-73; Appx80-97.

1. The Board's summary of the policies and precedent underlying ODP explaining that the doctrine protects the public's right to use a claimed invention once the patent has expired.

By way of background, the Board first explained the policies underlying ODP: namely, that it serves to (1) prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about, and (2)

⁴ In one of the underlying reexaminations (Control No. 90/014,454) regarding U.S. Patent No. 6,424,369, the Board sustained a first ODP rejection of the challenged claims in Collect's '369 patent (Appx49), finding the claims unpatentable over Collect's '036 patent and Tran (Appx42-44), but reversed an alternative ground, not at issue in this appeal, which relied on a different reference patent (the '626 patent) because the Board determined the Examiner misconstrued the priority date of the reference patent and the reference patent expired after the challenged patent due to having more PTA. Appx41; Appx49.

prevent multiple infringement suits by different assignees asserting essentially the same patented invention. Appx6-7 (citing *In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013)). The Board also indicated that a patentee can overcome a double patenting rejection by filing a terminal disclaimer under 35 U.S.C. § 253 and 37 C.F.R. § 1.321, which solves the two concerns of double patenting: making the later patent expire with the earlier patent and requiring a provision rendering the later patent unenforceable if it is not commonly owned with the earlier patent. Appx7 (citing 37 C.F.R. § 1.321 (b)(2), (c)(3), (d)(3); MPEP §§ 804.02(VI), 1490(VI)(A), (IX)); *see also Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1213-14 (Fed. Cir. 2014) (discussing longstanding CCPA decisions permitting the use of a terminal disclaimer under 35 U.S.C. § 253 to overcome ODP). But the Board noted that a terminal disclaimer over an expired reference patent cannot cure ODP. Appx7 (citing *Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 592 F.3d 1340, 1347-1348 (Fed. Cir. 2010) (explaining that by not disclaiming prior to expiration of the reference patent, the patentee “wrongly purports to inform the public” that its patent is still in force).

The Board next examined how courts have determined which patent is the “later” patent in an ODP analysis. Appx8. In particular, in an ODP analysis involving a patent that issued from an application filed after the June 8, 1995 enactment of the Uruguay Round Agreements Act (“URAA”), which changed the term of a patent from 17 years after issue to 20 years from the earliest filing date of any non-

provisional U.S. application to which that patent claims priority, the “later” patent is dictated by the expiration date of the patent. *Id.*

But under the Patent Act, patent term can also be extended or adjusted, thus it is not always the case that a URAA patent, such as those issued to Collect, expires 20 years from its effective filing date. The Board explained that under § 154(b), PTA is available to adjust the term based on certain delays by the USPTO during prosecution, and, under § 156, PTE may extend the term based on certain regulatory delays, such as when the Food and Drug Administration reviews a new drug for marketing approval. Appx9 (citing 35 U.S.C. §§ 154(b), 156).

The Board next reviewed this Court’s decisions concerning the interplay between double patenting and §§ 154(b) and 156 of the Patent Act. Appx9-12. In particular, in examining *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317 (Fed. Cir. 2007) (holding that if a patent is terminally disclaimed because of ODP, PTE is added from the expiration date resulting from that disclaimer, rather than the original expiration date) and *Novartis AG, et al., v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018) (finding that double patenting should be evaluated on a challenged patent’s pre-PTE expiration date inclusive of any terminal disclaimers), the Board noted that the Court’s rationale in both cases was premised on a reliance of the language relating to terminal disclaimers in the PTA statute (35 U.S.C. § 154(b)(2)(B)), that is absent from the PTE statute (35 U.S.C. § 156). Appx10. Specifically, the PTA statute contains a cutoff for terminal disclaimers (excluding patents in which a terminal disclaimer was

filed from the benefit of PTA beyond the expiration date specified in the disclaimer), while the PTE statute has no such cutoff. *Id.* citing (35 U.S.C. § 154(b)(2)(B) (stating “[n]o patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.”).

The Board noted that “[g]iven this relationship between double patenting and terminal disclaimers and given the holding in *Merck v. Hi-Tech* that a terminal disclaimer applies before PTE, the Federal Circuit not surprisingly held as a logical extension [in *Novartis v. Ezra*] . . . that double patenting also should be considered before a PTE.” Appx11 (citing *Ezra*, 909 F.3d at 1373-1374). The Board further noted the Court’s reasoning that if a patent, prior to considering any PTE, should have been terminally disclaimed as a result of ODP, but was not, the patent could be invalidated. *Id.* (citing *Ezra*, 909 F.3d at 1374). The Board also explained that in *Ezra*, the Court found that the policies underlying ODP did not apply because the challenged patent had an *earlier* filing date, issue date, and pre-PTE expiration date than the reference patent. Appx12 (citing *Ezra*, at 1373-1375 (emphasis added)). (Thus, no terminal disclaimer was necessary, and ODP did not apply.)

Against this backdrop, and as further explained below, the Board determined that Collect’s arguments were without merit and affirmed the Examiner’s rejection of the claims.

2. The Board’s rejection of Collect’s argument that ODP cannot truncate a timewise extension of patent term that is due to PTA.

The Board was not persuaded by Collect’s interpretation of *Ezra* and *Merck* to equate PTE and PTA and argue that ODP cannot be used to “cut off [any] statutorily-authorized time extension.” Appx12-16. The Board found that Collect had ignored the actual holding in *Ezra* and the plain text of Section 154 as compared to Section 156. Appx13.

First, the Board reiterated that *Ezra* confirms that a double patenting analysis should be done even if a patent has PTE, and that analysis is performed using the challenged patent’s original expiration date, inclusive of any terminal disclaimer. Appx13 (citing *Ezra*, 909 F.3d at at 1374). In other words, if a patent under its original expiration date should have been, but was not, terminally disclaimed because of an ODP issue, then the Court’s ODP caselaw would apply and the patent could be invalidated irrespective of any subsequent PTE granted to the patent. *Id.* As such, in *Ezra*, the ’229 patent was filed earlier, issued earlier, and expired earlier (under its pre-PTE expiration date), and thus there was no ODP issue and it did not qualify as an OPD reference. *Id.*

Second, the Board noted that the Court’s decisions in *Merck* and *Ezra* were predicated on a difference in the statutory language of Sections 154(b) and 156, and contrasted Section 154’s express exclusion of PTA in patents in which a terminal disclaimer was filed, to the absence of such a provision regarding PTE in Section 156.

Appx13 (citing *Merck* at 1322 and *Ezra* at 1373-1374). Accordingly, the Board determined that the holdings in *Ezra* and *Merck* as to the relationship between ODP and PTE are not similarly applicable to PTA. Appx13.

Third, the Board itself evaluated the statutory language in Section 154 and determined that the provision is clear that PTA cannot adjust a term beyond the expiration date in any terminal disclaimer. Appx14 (citing 35 U.S.C. § 154(b)(2)(B)). Thus, as recognized in *Ezra* and *Merck*, the Board found that “unlike a PTE under § 156, a PTA under § 154 shall *not* extend the term of a patent past the date of any terminal disclaimer.” Appx14.

Fourth, because Congress had addressed the issue of terminal disclaimers in Section 154, and such disclaimers arise almost exclusively to overcome ODP, the Board also found the statutory limitation on terminal disclaimers tantamount to Congress addressing ODP itself. Appx14. Appx14 (citing *Van Ornum*, 686 F.2d 937, 948 (C.C.P.A. 1982); 37 C.F.R. § 1.321(c), (d); MPEP § 1490(II); *Ezra* at 1373-1374). The Board further observed that ODP and terminal disclaimers are two sides of the same coin: representative of the problem and the solution. Appx15. Thus, the Board extended the logic presented in the statute to apply when a double patenting issue is presented with respect to a patent that has PTA. To that point, the Board noted that in one of the underlying reexaminations (Control No. 90/014,454), the Board had sustained the ODP rejection of the challenged claims in Collect’s ’369 patent, but reversed one of the two grounds the Examiner had relied upon because the cited

reference patent in that ground had expired *after* the challenged patent due to having more PTA, and thus did not qualify as an ODP reference. Appx15; Appx41; Appx49.

Dismissing Collect's arguments that the Board should apply the pre-PTA expiration date in determining if there exists a timewise extension of the right to exclude, the Board then circled back to the policies underlying ODP and, citing to *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. Of Rheumatology Tr.*, 764 F.3d 1366, 1373 (Fed. Cir. 2014) and *In re Fallaux*, 564 F.3d 1313, 1319 (Fed. Cir. 2009), reiterated that a crucial purpose of ODP is to prevent an inventor from securing a second, later expiring patent, including patents that have different terms due to examination delays at the USPTO. Appx15.

The Board thus determined that unlike *Ezra*, ODP (and terminal disclaimers) should be considered after the expiration date that includes any PTA. Appx16. The Board also explained that applying different dates for double patenting versus terminal disclaimers would create inconsistent results. Appx16, fn. 6.

3. The Board's finding that Collect's reliance on a district decision that held PTA cannot be truncated by ODP to be unpersuasive

The Board was also unpersuaded by Collect's reliance on a prior district court decision in *Mitsubishi Tanabe Pharma Corp. v. Sandoz, Inc.*, 533 F. Supp. 3d 170 (D.N.J. 2021), to argue that the Board should reverse the Examiner's rejections. Appx16-18. In that case, the district court held that because the reference patent (U.S. Patent No. 8,222,219) and challenged patent (U.S. Patent No. 7,943,788) were part of the same

family, and the difference in patent term was due (largely) to PTA, the reference patent did not qualify as an ODP reference under this Court's decision in *Ezra*. *Mitsubishi*, at 214. For the reasons discussed below, the Board did not give the district court's decision any weight when affirming the Examiner's rejections here.

In particular, the Board first noted that another district court decision, *Magna Elecs., Inc. v. TRW Automotive Holdings Corp.*, No. 12-cv-654, 2015 WL 11430786 (W.D. Mich. Dec. 10, 2015), had come out the other way, holding that the reference patent qualified as an ODP reference against the challenged patent, where the difference in patent term was due solely to PTA. Appx16. Second, the Board explained that the district court had failed to consider that ODP can apply to two patents that have the same filing date, the same issue date, and the same expiration date. Appx17 (citing *Underwood v/ Gerber*, 149 U.S. 224 (1893)). And that, in such a scenario, a terminal disclaimer would still be needed to ensure that the two patents remain commonly owned. Appx17 (citing *Sandy MacGregor Co. v. Vaca Grip Co.*, 2 F.2d 655, 657 (6th Cir. 1924); *Van Ornum*, 686 F.2d at 945 (similarly summarizing *Underwood*)).

The Board also took note of legal and factual errors underlying the district court's decision in *Mitsubishi*. In particular, based on the district court's discussion of the *Ezra* decision and difference between Sections 154 and 156, it was apparent to the Board that the district court had not understood that a terminal disclaimer is the standard means to cure double patenting, and thus had overlooked the rationale behind the Federal Circuit's holding *Ezra* that because PTE, as compared to PTA, is not cut

off by terminal disclaimers, ODP does not invalidate a validly obtained PTE. Appx17 (citing *Mitsubishi*, F. Supp. 3d at 213, at n. 45). Further, because the district court also confused when the challenged patent would have expired relative to the reference patent, it was not clear to the Board whether the district court had understood the facts of the case in rendering its decision. Appx17 (comparing *Mitsubishi*, at 214 (“absent the PTA granted to the ’788 Patent, both the ’788 Patent and the ’219 Patent would have the same expiration date”), *with id.* (“but for the § 154(b) PTA, the ’788 Patent would have expired before the ’219 Patent”). Finally, the Board found that in *Mitsubishi*, the challenged patent issued before the reference patent, unlike the facts related to Collect’s challenged patent. Appx17-18.

4. The Board’s determination that ODP can apply to reference and challenged patents with the same expiration date

Although the Board decided that, based on this Court’s precedent and the differences in Sections 154 and 156, ODP should be considered after any PTA is applied in calculating a patent’s expiration date, the Board also noted that, as a policy matter, the doctrine of ODP would render Collect’s claims unpatentable even when applied to the pre-PTA expiration dates of the challenged and reference patents. Appx18-20; *Underwood*, 149 U.S. at 224 (affirming a second patent as void when both patents had the same filing date, issue date, and expiration date). The Board explained that because the (later-issued) challenged patent claims obvious variants of (an earlier-issued) reference patent, a terminal disclaimer would still be necessary to ensure that

the patents remain commonly owned, which is crucial to accomplish the second goal of ODP: preventing multiple infringement suits by different assignees asserting essentially the same patented invention. Appx19 (citing *Hubbell*, 709 F.3d at 1145; *Sandy MacGregor*, 2 F.2d at 657; *Van Ornum*, 686 F.2d at 945).

Cellect did not address the application of ODP to patents with the same expiration date, but instead argued that there has been no harassment by multiple assignees because the patents have been commonly owned so far and had since expired. Appx19. The Board explained, however, that the risk still remained for multiple assignees to seek past damages as the six-year statutory time limitation for such damages had not yet expired. Appx19 (citing 35 U.S.C. § 286). And Cellect's assertion that the inventor had submitted a declaration that the patents will be maintained by the same owner was not determinative because a situation could arise, for example, where the patents are split between creditors in a bankruptcy proceeding. Appx19-20. Further, the Board noted that there is no need to wait until there is actual harassment by multiple assignees, as the goal behind ODP and using curative terminal disclaimers is to preemptively prevent the risk of such harassment. Appx20 (citing *Van Ornum*, 686 F.2d at 944). In sum, the Board provided alternative justifications for why the Examiner's ODP rejection was proper: (1) the timewise extension of patentably indistinct claims beyond the expiration date of the reference patent brought about by the difference in patent term due to PTA, or (2) because Cellect

owns two patents that claim obvious variants and there exists a risk for harassment by multiple assignees. Appx20-21.

5. The Board's rejection of Collect's argument that under equitable principles the ODP rejection should not stand

The Board was also unpersuaded by Collect's arguments, that under equitable principles, the ODP doctrine should not be applied to Collect's challenged patents, because no terminal disclaimer could be filed during the reexamination proceedings and there is no evidence of gamesmanship. Appx22-23. The Board clarified that the inequity that underlies ODP stems from the patentee's enjoyment of a second patent's term beyond the expiration of the first patent. Appx22 citing *Boehringer*, 592 F.3d at 1347-48; *In re Lonardo*, 119 F.3d 960, 965 (Fed. Cir. 1997); *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 197-98, 202 (1894); *Odiorne v. Amesbury Nail Factory*, 18 F.Cas. 578, 579 (C.C.D.Mass.1819); *Gilead*, 753 F.3d at 1212. And here Collect enjoyed its right to enforce the full term of its first (reference) patent. Appx24.

C. The Board's finding that the reexamination request presented a substantial new question of patentability and was properly granted

The Board was unpersuaded by Collect's argument that there was no substantial new question of patentability in the reexamination proceeding because the Examiner in the original prosecution was aware of the applications that matured into the reference and challenged patents, and thus would have made a double patenting rejection if the Examiner believed that such a rejection was warranted. Appx21-22. In

particular, the Board found that there was insufficient evidence that ODP was actually considered during the original prosecution. Appx21-22. The Board also noted that regardless of what ideally should have occurred during the original prosecution, the reexamination process exists because items sometimes get overlooked or errors are made. Appx21 (citing *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 604 (Fed. Cir. 1985) (“The reexamination statute’s purpose is to correct errors made by the government . . . and if need be to remove patents that should never have been granted.”), *on reh’g*, 771 F.2d 480, 481 (Fed. Cir. 1985)(denying the petition in relevant part)).

Accordingly, the Board affirmed the Examiner’s ODP rejections as to each of Collect’s challenged patents.

IV. Summary of the Argument

Collect does not dispute that the challenged patents and reference patents are commonly owned, that the challenged patents expired after the reference patents, and that all of the challenged claims are patentably indistinct over claims in the reference patents. Following this Court’s precedent in *AbbVie* and *Gilead*, the Board correctly determined that Collect’s claims in the challenged patents are unpatentable under ODP over the claims in the cited reference patents. Collect’s legal and equitable arguments to the contrary are unpersuasive.

First, Collect challenges whether the Board’s ODP determination is legally proper when the difference in patent term between the reference patents and the challenged patents is due to statutorily granted PTA. In particular, Collect argues that

the Board erred in not extending this Court's holding in *Ezra*, 909 F.3d at 1373, that ODP does not invalidate a validly obtained PTE, to find that ODP does not apply to statutorily authorized PTA. But Collect's arguments ignore one of the crucial purposes of the double patenting doctrine: it is designed to prevent an inventor from securing a second, later expiring patent for the same/obvious invention. This bedrock principle has animated the courts and Congress when adjudicating cases and enacting legislation related to these issues. As such, as the Board correctly found, this Court has explained on repeated occasions that patents claiming overlapping subject matter, that have different patent terms due to PTA, give rise to issues of ODP. And this Court's narrow decisions in *Ezra* and *Merck*, which were predicated on the statutory differences between the PTA statute (in which terminally disclaimed patents are exempt from such statutorily authorized time) and the PTE statute (in which there is no such exemption), do not change this outcome. Further, because Congress included this distinction, it understood that PTA can be limited when a terminal disclaimer is necessary to overcome an ODP issue, and that ODP should apply here.

Second, Collect argues that, under equitable principles, the rejection should not stand when no curative terminal disclaimer can be filed over the expired reference patents and there was no evidence of gamesmanship. But this argument fares no better. As the Board properly found, ODP also applies to diminish the risk of future harassment from multiple assignees, and further, the doctrine can be applicable to patents where there is no actual timewise extension of the right to exclude. Because

the later-issued patent claims obvious variants of the earlier-issued reference patent, a terminal disclaimer would be necessary to ensure that the patents remained commonly owned. It is of no moment that by the time the Board applied the doctrine, Collect's reference patents had expired and it could no longer file a terminal disclaimer to overcome the rejection. Collect could have filed such a disclaimer in the original prosecution of the challenged patents, but chose not to. Moreover, at the time of the reexamination, the statutory time limitation for past damages had not expired, and the Board correctly explained that the risk remained for litigation harassment as the patents could be involuntarily assigned to different owners due to a bankruptcy proceeding.

Finally, Collect also contends that there was no substantial new question of patentability to warrant reexamination of Collect's challenged patents. But, consistent with 35 U.S.C. § 303(a) and this Court's decision in *Vivint*, 14, F. 4th. 1342, there is no evidence the USPTO ever considered and decided ODP during the original prosecution of the applications that matured into the challenged patents, and therefore the reexamination was properly instituted as to each proceeding. The Court should thus affirm the Board's decisions below.

V. Argument

A. Standard of review

Collect bears the burden of showing that the Board committed reversible error. *In re Watts*, 354 F.3d 1362, 1369 (Fed. Cir. 2004). The Board's actions may not be set

aside unless they are “arbitrary, capricious, an abuse of discretion, unsupported by substantial evidence, or otherwise not in accordance with law.” *In re Sullivan*, 362 F.3d 1324, 1326 (Fed. Cir. 2004); 5 U.S.C. § 706(2)(A).

The ultimate conclusion of obviousness type double patenting is a question of law that this Court reviews de novo. *In re Emert*, 124 F.3d 1458, 1460 (Fed. Cir. 1997). Whether a substantial new question of patentability exists is a question of fact reviewed for substantial evidence. *See In re Swanson*, 540 F.3d 1368, 1375 (Fed. Cir. 2008). “Substantial evidence is more than a mere scintilla and means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *Celgene Corp. v. Peter*, 931 F.3d 1342, 1349 (Fed. Cir. 2019) (citations omitted).

B. The Board correctly determined that the cited reference patents render Collect’s challenged patents unpatentable under the ODP doctrine.

There is no dispute that Collect’s challenged patents and reference patents are commonly owned, that the challenged patents expired after the reference patents, that all of the challenged claims are patentably indistinct over the reference claims, and that Collect could not file a terminal disclaimer to retroactively cure an ODP rejection over the reference patents. As the Board properly found, Collect enjoyed an unjustified timewise extension of its ability to exclude the public from practicing its claimed inventions, and thus correctly concluded that the patents are unpatentable under ODP. Appx15.

On appeal, Collect argues that, as a legal matter, the reference patents cannot be used as a basis for an ODP determination because the difference in term is due to statutorily granted PTA, and, as an equitable matter, the rejection should not be enforced because Collect cannot file a terminal disclaimer to obviate the ODP rejection and there was no evidence of gamesmanship. But, as explained below, none of Collect's arguments challenging the merits of the Board's decision pass muster.

1. This Court's precedent is clear that ODP applies to timewise extensions of the right to exclude due to PTA and *Ezra*'s narrow holding does not change that outcome.

Collect and amici assert that the Board misinterpreted this Court's holdings in *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317 (Fed. Cir. 2007) and *Novartis AG v. Ezra Ventures, LLC*, 909 F.3d 1367 (Fed. Cir. 2018) and erred in treating PTA and PTE differently for purposes of double patenting. Br. at 22-25; *see also e.g.*, D.E. No. 31 at 10; D.E. No. 28 at 5; D.E. No. 25 at 13. But contrary to Collect's and amici's assertions, and as the Board correctly determined, these cases do not hold that ODP does not apply to patents that have extended term due to PTA. In *AbbVie* this Court reaffirmed its holding in *Gilead* that expiration dates drive the ODP analysis in the post-URAA context, and that even related "[p]atents claiming overlapping subject matter that were filed at the same time still can have different patent terms due to examination delays at the PTO." *AbbVie*, 764 F.3d at 1373 (citing, *inter alia*, 35 U.S.C. § 154(b)). The Court in *AbbVie* thus concluded that "[w]hen such situations arise, the

doctrine of obviousness-type double patenting ensures that a particular invention (and obvious variants thereof) does not receive an undue patent term extension.” *Id.* And *Ezra*’s narrow holding as to the effect ODP may have on PTE, which is premised on different statutory language than PTA, does not change that result.

As an initial matter, *Ezra* does not hold that ODP is not applicable when a patent has PTE, but instead reaffirms that a double patenting analysis should be done as of the relevant patents’ original filing dates, prior to considering the effect of any extension. *Ezra*, 909 F.3d at 1374 (“We agree . . . if a patent is terminally disclaimed to another patent to overcome an [ODP] rejection and *then term-extended under § 156* (as in *Merck*), it necessarily will expire after the patent to which it had been subject to an [ODP] rejection.”) (emphasis added). As the Board explained, under *Ezra*’s reasoning, if a patent under its original expiration date without a PTE should have been (but was not) terminally disclaimed because of ODP, then the Court’s ODP law would apply and the patent could be invalidated. Appx13 (citing *Ezra*, 909 F.3d at 1374). As such, if in *Ezra* the reference patent had raised issues of ODP under its pre-PTE expiration date, but could not be terminally disclaimed because the reference patent had since expired, ODP would apply and invalidate the patent, irrespective of the PTE.

Cellect appears to ignore this determination by the Board and largely hangs its arguments on a single sentence in the *Ezra* decision, in which the Court observed the “judge-made doctrine” of double patenting should not “cut off a statutorily-authorized time *extension*,” to argue that double patenting cannot likewise limit

statutorily granted PTA. Br. at 25 citing *Ezra*, 909 F.3d at 1375 (emphasis added). But, this sentence cannot be viewed in a vacuum as Collect invites this Court to do. As the Board correctly determined, the holding in *Ezra* concerns the application of ODP on a patent with PTE, which is premised on a different statutory section of the Patent Act than PTA. Appx12-14. In particular, Section 154(b)(2)(B) states that “[n]o patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer,” but Section 156 contains no such disclaimer. *Compare* 35 U.S.C. § 156 *with* 35 U.S.C. § 154(b). Indeed, the *Ezra* and *Merck* Courts expressly relied on this language to distinguish 35 U.S.C. § 156 from 35 U.S.C. § 154(b).

In particular, in *Merck*, this Court addressed the impact of a terminal disclaimer filed to overcome an ODP rejection during examination on a subsequently-received § 156 PTE. *Merck*, 482 F.3d at 1321-1324. The Court first turned to the statutory language of § 156, noting that (1) it does not expressly reference terminal disclaimers, and (2) if the statutory requirements are met, the patent term “shall be extended.” *Merck*, 482 F.3d at 1322 (citing 35 U.S.C. § 156. But in comparison, the Court found that § 154(b)(2)(B) expressly excludes patents in which a terminal disclaimer was filed from the benefit of a term adjustment for USPTO delays. *Merck*, at 1322; 35 U.S.C. § 154(b)(2)(B) (“No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.”). Construing both sections 156 and 154, this Court thus concluded that

by expressly referring to terminal disclaimers in § 154(b) but not in § 156, Congress clearly intended for terminal disclaimers to bar patents from receiving the benefit of PTAs based on PTO delay but not prevent patents from receiving PTEs due to FDA regulatory delay. *Merck*, 482 F.3d at 1322. Moreover, the Court noted that under Section 156, Congress was aware of the concerns over the effects of extending multiple related patents, and chose to provide the patentee with the option to select to extend the term of only one such patent, but gave the patentee the choice as to which patent to extend, as long as the requirements for PTE are met. *Merck*, 482 F.3d at 1323. That statutory difference between PTE and PTA was reiterated in *Ezra*, and the Court held (as a “logical extension” of *Merck*) that ODP does not invalidate a validly obtained PTE in that particular factual scenario. *Ezra*, at 1373-1374. As such, *Ezra*’s holding cannot be extended to apply equally to PTA, as Collect asserts. Br. at 25. To expand *Ezra*’s exception for § 156 PTEs to § 154 PTAs, as Collect asserts, flouts the reasoning for creating the narrow PTE exception in the first place, as well as this Court’s holdings in *Gilead* and *AbbVie*.

In an effort to overcome *AbbVie*—which recognized that an unjustified timewise extension could arise in the context of PTA—Collect remarks, in a footnote, that *Ezra* post-dates *AbbVie* and contends that *AbbVie* is distinguishable because, here, the patent owner did not seek to obtain a second, later expiring patent for an invention claimed in an earlier-issued patent Br. at 25, fn. 2 (citing *Ezra*, 909 F.3d at 1375). First, arguments found only in footnotes are not preserved and thus deemed

forfeited. *See Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1294 (Fed. Cir. 2012).

Second, Collect's argument is non-sensical as the Court in *AbbVie* noted that an undue extension of the right to exclude the public can arise when related patents are awarded different PTAs. *AbbVie*, at 1373. Thus, contrary to Collect's argument, *Ezra* should not be extended to hold that patents with extended term due to PTA cannot be subject to double patenting rejections.

2. The contrast in statutory language between Section 154 and Section 156 makes clear that terminal disclaimers cut PTA, but not PTE, and the Board's determination is consistent with *Ezra*

Collect next takes issue with the Board's independent determination (and consistent with this Court's reasoning in *Ezra/Merck*) that unlike a PTE under Section 156, which contains no additional limitations once the statutory conditions are met, Section 154 is clear that PTA shall not extend the term of a patent past the date of any terminal disclaimer. Br. at 26-32. Collect argues that the Board's statutory interpretation would effectively eviscerate § 154(b), as it "would make adjustments unavailable to related patents, because such adjustments would also invalidate them." Br. at 27. Collect's argument falls short for several reasons.

First, Collect improperly conflates the operation of PTA and ODP. The ODP analysis involves specific, independent steps to determine, for example, if the claims in the challenged patent are not patentably distinct from the claims in the reference patent, *AbbVie*, 764 F.3d at 1374; thus, ODP does not implicate all "related patents."

Consistent with this Court’s precedent, PTA would only render related patents unpatentable under ODP when there is a timewise extension beyond the reference patent and the test for ODP is satisfied. Appx15; *see also AbbVie*, at 1373; *Fallaux*, at 1319. To that end, the Board explained that in one of the underlying reexaminations (Control No. 90/014,454), the Board had sustained the ODP rejection of the challenged claims in Collect’s ’369 patent, but reversed one of the two grounds the Examiner had relied upon because the cited reference patent in that ground had expired *after* the challenged patent due to having more PTA, and thus did not qualify as an ODP reference. Appx15; Appx41; Appx49.

Second, in most cases, a terminal disclaimer can be filed to obviate an ODP determination. *In re Robeson*, 331 F.2d 610, 613-15 (C.C.P.A. 1964) (“[T]he only real objection to granting appellant’s application is an extension of the monopoly. The terminal disclaimer, which Congress has expressly provided, removes any danger of such result[.]); *Gilead*, 753 F.3d at 1213-14 (citation omitted) (“obviousness-type double patenting could be overcome by filing a terminal disclaimer, which had been provided for in section 253 of the 1952 Patent Act for that very purpose.”) Indeed, Collect’s suggestion that, as a consequence of the Board’s decision, patent applicants would need to file a preemptive terminal disclaimer (*see. e.g.*, Br. at 27) should be taken to heart—that is precisely the means Collect could have taken to avoid an ODP determination when, as is the case here, related patents, with different PTAs, claim patentably indistinct inventions (an issue that Collect notably has conceded here).

Collect's complaint that nothing in the plain language of Section 154 demonstrates that Congress intended for PTA to result in the need for a terminal disclaimer (Br. at 28), as well as its assertion that a provision about terminal disclaimers cannot serve as a Congressional proxy for when to conduct an ODP analysis (Br. at 39), are belied by this Court's own construction of Sections 154 and 156 in *Ezra*, and its determination as to when ODP should apply. *Ezra*, at 1374. The Board observed that ODP and terminal disclaimers are two sides of the same coin: representative of the problem and the solution. Appx15. That Congress limited the application of PTA when a disclaimer is present demonstrates Congress' intent to apply ODP when a double patenting issue is presented with respect to a patent that has a timewise extension due to PTA. Appx15. Further, ODP is a longstanding doctrine based on the bargain that an inventor makes where in exchange for a patent, the inventor must fully disclose his invention and promise to permit free use of it at the end of the patent's term, and this basis has been both recognized and applied by the Federal Courts long before Congress passed the PTA statute in 1999. *Gilead*, 753 F.3d at 1212-14 (discussing history of ODP, dating back to 19th century case law); Pub. L. No. 106-113, § 1000(a)(9), 113 Stat. 1501, 1536 (1999) (codified at 35 U.S.C. § 154(b)). Congress is presumed to legislate against the backdrop of existing law. *Procter & Gamble Co. v. Kraft Foods Glob., Inc.*, 549 F.3d 842, 848 (Fed. Cir. 2008).

Collect's assertion that, in practice, the USPTO could not apply the Board's proposed distinction between extensions and adjustments without creating

inconsistencies (Br. at 40) is without merit. Indeed, in *Ezra*, the Court contemplated essentially the same scenario Collect raises. *Ezra*, at 1374. In particular, the Court made clear that if under its original expiration date, without PTE, a patent should have been (but was not) terminally disclaimed because of ODP, then the ODP caselaw should apply and the patent could be invalidated. In other words, without considering PTE, if there is a timewise extension of patentably indistinct subject matter due to PTA (or otherwise), ODP could apply. Moreover, the “inconsistencies” between PTA and PTE mentioned in Collect’s brief arise not from the USPTO’s practice, but rather from the differences between the statutory language of sections 154(b) and 156, as discussed above.

Collect’s argument that patent term restoration provisions do not trigger the policy concern of an unjust timewise extension is unavailing and contrary to the jurisprudence of this Court. (Br. at 40.) This Court held in *AbbVie* that such a concern was triggered, and *Ezra* did not (and could not) overrule *AbbVie* or otherwise cast doubt on its application to this case. Appx15; *AbbVie*, at 1373; *Ezra*, at 1375.

3. Collect’s reliance on two prior district court decisions is misplaced.

Collect also points to two prior district court decisions, *Mitsubishi Tanabe Pharma Corp. v. Sandoz Inc.*, 533 F. Supp. 3d 170 (D.N.J. 2021) and *Amgen, Inc. v. Sandoz Inc.*, No. 18-11026 (MAS) (DEA), 2021 WL 5366800 (D.N.J. Sept. 20, 2021), *appealed on other grounds*, No. 22-1147 (lead) (Fed. Cir. Nov. 12, 2021)), as allegedly persuasive

authority in an effort to argue that the Court here should likewise expand *Ezra*'s holding to PTAs. Br. at 32-39. First, this Court is not bound by decisions rendered by district courts matters in that fall within the exclusive subject matter responsibility of the Court. *See Minnesota Min. & Mfg. Co. v. Norton Co.*, 929 F.2d 670, 672 (Fed. Cir. 1991) (citation omitted). Second, Collect's reliance on these prior decisions is misplaced because the facts are not analogous to the case at hand and the courts did not consider the statutory differences between Sections 154 and 156. For instance, unlike the patents at issue here, in *Mitsubishi* and *Amgen* the challenged patent was the earlier filed, earlier issued, but later expiring patent. *Mitsubishi*, 533 F. Supp. 3d at 211-212; *Amgen*, 2021 WL 5366800, at *26. Thus, in *Mitsubishi*, the court found *AbbVie* to be inapplicable. *Mitsubishi*, 533 F. Supp. 3d at 213, n.43. Further, as the Board noted, it did not appear that the *Mitsubishi* district court properly considered the statutory differences in Sections 154 and 156 in its discussion of terminal disclaimers; rather, the district court only noted that PTA cannot extend term that has been disclaimed and that no argument was made that a disclaimer was required in the case at hand. Appx17; *Mitsubishi*, F. Supp. 3d at 213, at n. 45.

4. The Board's decision is properly grounded in public policy because there exists an unjustified timewise extension and a risk of litigation from multiple assignees.

Collect's argument that the Board's decision is improper because Collect's challenged patents do not implicate the public policy reasons justifying the ODP

determination is unavailing. Br. at 41-45. As Collect notes in its brief (Br. at 42), there are two public policy concerns underlying ODP: (1) to prevent an unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about, and (2) to avoid the risk of harassment of an alleged infringer by multiple assignees asserting essentially the same patented invention. *See In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013) (citations omitted). Here, both policies are implicated.

As already discussed above, the Board properly relied on the *AbbVie* decision in determining that Collect enjoyed an unjustified timewise extension of the right to exclude the public from practicing Collect's claimed inventions. Appx15. Collect's and amici's assertions that there must be a predicate showing by clear evidence that Collect "purposely manipulate[d] the system" or committed other specific prosecutorial gamesmanship for the extension to be unjustified are a red herring. Br. at 42; *see also* e.g., D.E. no. 25 at 5-13. While cases like *Gilead* have described potential gamesmanship issues that may result if the ODP inquiry for post-URAA patents relied on issuance date instead of expiration date, such issues were not described as prerequisites to ODP and the cases did not limit the ODP doctrine to such scenarios. *Gilead*, 753 F.3d at 1215. Indeed, in *AbbVie*, which further affirmed *Gilead*, this Court explained that ODP may arise under typical examination situations concerning post-URAA patents (*e.g.*, when PTA is awarded) because the doctrine is designed to prevent an inventor from securing a second, later expiring patent for the same

invention, including patents that were filed at the same time but have different patent terms due to PTA. *AbbVie*, 764 F.3d at 1373 (citing 35 U.S.C. § 154(b)); *see also Gilead*, 753 F.3d at 1215 (“[T]he primary ill avoided by enforcement of the double patenting doctrine is restriction on the public’s freedom to use the invention claimed in a patent and all obvious modifications of it after that patent *expired*.”) (emphasis in original). As such, while *Gilead* and *AbbVie* describe different factual scenarios where the potential for gamesmanship may or may not occur, there is no scienter requirement as alleged by Collect and amici.

Further, Collect’s (and amici’s) reliance on cases such as *Novartis Pharm. Corp. v. Breckenridge Pharm., Inc.*, 909 F.3d 1355 (Fed. Cir. 2018), to argue that there is no basis to conclude that Collect’s extension was unjustified is misplaced. Br. at 43; *see also e.g.*, D.E. no. 25 at 6-9. As to the *Breckenridge* case, the Court there found that the facts did not give rise to the type of gamesmanship concerns described in *Gilead* and *AbbVie* (as to post-URAA patents) because one of the patents was a pre-URAA patent such that the issuance date “serve[d] as a reliable guide for assessing whether a patent may serve as a double patenting reference against another patent,” *Breckenridge*, 909 F.3d at 1366, and the difference in the pre- and post-URAA patent terms was due to happenstance of an intervening change in patent term law in the URAA, *id.* at 1364. Also, unlike Collect’s patents, in *Breckenridge*, the challenged patent was earlier filed, earlier issued, but had a later expiration date. *Id.* at 1360.

Nevertheless, Collect's argument that, because the Court has emphasized the importance of the specific facts of a case in the cases cited above, the Court now should weigh heavily the relationship amongst Collect's patents in applying ODP in this appeal (Br. at 43) is of no moment because that is precisely what the Board did. The Board evaluated the particular facts as to how Collect secured second, later expiring patent claims for patentably indistinct inventions, and determined that such claims were unpatentable under ODP.

As to the second policy underlying ODP, Collect argues that the risk of harassment by multiple litigants is speculative and should not be used as a basis for affirming an ODP rejection in cases where the patents have a shared expiration date. Br. at 44. But the Board's ODP determination is properly grounded in the policy aimed at avoiding potential harassment suits from multiple assignees owning patents on obvious variants of the same invention. In particular, the Board explained that even if Collect's patents had the same expiration date (as argued by Collect), because the later-issued patent claims obvious variants of the earlier-issued reference patent, a terminal disclaimer would be necessary to ensure that the patents remained commonly owned, as the disclaimer requires a provision that the patent is rendered unenforceable if common ownership is not maintained. Appx19; 37 C.F.R. § 1.321(c)(3); *see also In re Fallaux*, 564 F.3d 1313, 1318-1319 (Fed. Cir. 2009) (finding that the Board's obviousness-type double patenting rejection was justified because, although there was no timewise extension of the patent, there was the potential for

litigation harassment by multiple assignees). Because at the time of the reexamination, the statutory time limitation for past damages had not expired, the Board correctly explained that the risk remained for litigation harassment. Appx19 (citing 35 U.S.C. § 286). Indeed, Collect had already filed one lawsuit after the patents-at-issue had expired. Appx19. Moreover, the Board found that a declaration by Collect's co-founder promising not to assign the patents was insufficient, as there could be a bankruptcy proceeding splitting the patents among various creditors. Appx20. The Board further explained that there is no requirement to wait until actual harassment by multiple assignees, because the goal of ODP is to preemptively avoid the risk of such harassment. Appx20 (citing *Van Ornum*, 686 F.2d at 944).

C. The Board correctly determined that the reexamination requests raised a substantial new question of patentability.

Finally, Collect asserts that the reexaminations did not raise a substantial new question of patentability because the Examiner who examined the underlying applications was aware of the reference patents, did an interference search, and did not make an ODP rejection during the original prosecution. Br. at 45-52. But as the Board properly found, the agency correctly determined that the underlying reexamination requests raised a substantial new question of patentability under 35 U.S.C. § 303(a).

The Patent Act and this Court's precedent make clear that there is no presumption that if a reference is cited in the original prosecution, that it was

substantively considered as to patentability by the Examiner. 35 U.S.C. § 303(a) provides in relevant part:

(a) . . . On his own initiative, and any time, the Director may determine whether a substantial new question of patentability is raised by patents and publications discovered by him or cited under the provisions of section 301 of this title. *The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.*

35 U.S.C. § 303 (emphasis added). The italicized language took effect on November 2, 2002, and applies to determinations of substantial new questions of patentability (“SNQs”) that occurred after that date. The amendment restored the focus of the SNQ inquiry from whether a particular reference was considered to “whether the particular question of patentability presented by the reference in reexamination was previously evaluated by the PTO.” *In re Swanson*, 540 F.3d 1368, 1380 (Fed. Cir. 2008). Moreover, the Court recently clarified that a question of patentability is “new” until it has been considered and decided on the merits. *In re Vivint*, 14 F.4th 1342, 1349 (Fed. Cir. 2021) (citation omitted).

As the Board further noted, the reexamination process exists because sometimes issues get overlooked or errors are made in the original prosecution and the purpose of reexamination is to correct such errors. Appx22 (citing *Patlex*, 758 F.2d at 604). Here, as the Board properly found, there is insufficient evidence in the record that double patenting was actually considered and decided by the Examiner during the

original prosecution of the challenged patents; thus, a substantial new question of patentability did exist.⁵ Appx21.

D. Collect’s request that the Court not invalidate the challenged patents in their entirety is forfeited and unavailing.

Collect requests that if the Court applies ODP to its challenged patents, that the Court apply the rejection only to the period of the extension and not the entire patent. Br. at 52-53. First, Collect’s argument appears to have been forfeited, as Collect failed to make this particular argument to the Examiner and the Board. No circumstances exist that excuse Collect’s failure to raise this argument during the proceedings below and the Court should not exercise its discretion to review it now. *In re Google Tech. Holdings LLC*, 980 F.3d 858, 862 (Fed. Cir. 2020). Second, Collect’s request is unavailing because it is tantamount to a request for a retroactive terminal disclaimer—a terminal disclaimer that is filed after the expiration date of the reference patent. As the Court explained in *Boehringer*, when a patentee does not terminally disclaim the later patent before the expiration of the earlier related patent, “the patentee enjoys an unjustified advantage—a purported time extension of the right to exclude from the date of the earlier patent . . . and cannot undo this unjustified

⁵ The Board also noted that at the time the Examiner issues the notice of allowance, the Examiner does not necessarily know whether the resulting patent will receive any PTA. Appx22. Collect is correct that, because the challenged patents issued prior to January 14, 2013, the PTA would have been listed on the notice of allowance. Br. at 51; MPEP § 2733. But again, at bottom, there was no evidence that the Examiner considered and determined the issue of ODP in the original prosecution of Collect’s challenged patents.

timewise extension by retroactively disclaiming the term of the later patent because it has already enjoyed the rights it seeks to disclaim.” *Boehringer*, 592 F.3d at 1347-1348.

Collect’s reliance on the Board’s decision as to the ’369 patent does not help. In that proceeding, the Board determined that under one of the grounds of the rejection, there was no timewise extension as compared to the ’626 patent, because the ’626 patent expired after the challenged ’369 patent. Appx41. However, the Board affirmed the second ground of the rejection, finding that the challenged ’369 patent expired after the reference ’036 patent, and thus there was an unjustified timewise extension of the right to exclude as to that patentably indistinct subject matter. Appx43-45. As such, as to each of the challenged patents at-issue in this matter, Collect enjoyed an unjustified extension of its right to exclude.

E. Collect’s bare assertion that alternative ODP rejections based on a combination of references are unexplained by the Board is forfeited and largely moot.

Collect has not challenged the determination that the claims of the ’742 patent, the ’369 patent, the ’626 patent, and the ’621 patent are patentably indistinct from the claims of the respective reference patents cited in the underlying reexaminations. The Director does agree that Collect’s challenged patents rise or fall together based on the arguments Collect raised. But to the extent Collect is now asserting that the Board failed to explain how additional references, in combination with the reference patents, render the claims in the ’742 patent, the ’369 patent, and the ’626 patent unpatentable, that assertion is forfeited on appeal. *See Google Tech. Holdings LLC*, 980 F.3d at 862.

Moreover, as to the claims rejected in the '742 patent and the '626 patent, the Board affirmed the Examiner's rejections over two grounds: the reference patent itself, and the reference patent in combination with another reference. *See* Appx24; Appx73.

Thus, in those cases, this Court need not reach the alternative ODP rejections that the Examiner made, and the Board affirmed. Those arguments are nevertheless moot in view of Collect's general concession that the subject matter recited in claims of the challenged patent are patentably indistinct from those recited in the claims of the ODP reference patents.

VI. Conclusion

Because the Board's ultimate conclusion of obviousness-type double patenting in the underlying reexaminations is correct as a matter of law, and because the Board properly affirmed the Examiner's determination that each reexamination presented a substantial new question of patentability, this Court should affirm the Board's decisions that the challenged patent claims are unpatentable.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify pursuant to Fed. R. App. Proc. 32(a)(7) that the foregoing BRIEF FOR APPELLEE, DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE complies with the type-volume limitation required by the Court's rule. The total number of words in the foregoing brief, excluding the table of contents and the table of authorities, is 10,260 as calculated using the Word® software program.

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